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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,233	04/26/2000	PHILIPPE SEGUELA	641050.90021	3952

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LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,233

Applicant(s)

SEQUELA ET AL.

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-21, 38 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-21 and 41 is/are allowed.
- 6) ☒ Claim(s) 38, 40, 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Amendment filed 31 May 2005 has been entered. Claims 16-21 and 38-42 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 31 May 2005 have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 112

4. Claims 38, 40 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims recite or encompass the term "85% identical" and "human" which is ambiguous and the metes and bounds of the term is not clear. The term "% identical" is a relative term whose metes and bounds are not clear because one skilled in the art requires specific algorithms in order to calculate % identity. Applicants argue that the % identity alignment provided by the examiner is incorrect because the applicants' alignment gives different results. Thus, the metes and bounds of the term % identity is ambiguous without the specific algorithm recitation in the claims. Furthermore, it is not

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clear to one skilled in the art when an "85% identical" polypeptide is human or when it is not human or any other species unless it is the specific human species of SEQ ID NO:2 disclosed in the specification.

5. Claims 38, 40 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims recite "85% identical" and "human" which encompass variants of SEQ ID NO:2 as well as the claimed limitation of being "human". However, one skilled in the art cannot envision all the various species of peptide which is "human" and "85% identity with SEQ ID NO:2 with the function of being inhibited by amelioride". The specification discloses the specific species of SEQ ID NO:2 and the claims encompass a large number of species which cannot be envisioned and whose function is not specifically defined. While the species of SEQ ID NO:2 is human and functions to inhibit amelioride, one skilled in the art cannot envision the difference in structure from SEQ ID NO:2 which provides the characteristic of being human. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the genus of polynucleotide structure cannot be envisioned.

Priority

6. Applicant's claim for priority under 35 U.S.C. 119(a-d) is acknowledged.

However, the foreign application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 38, 40 and 42 of this application for the reasons provided above in the 35 USC 112 rejections. See MPEP 706.02.

Claim Rejections - 35 USC § 102

7. Claims 38, 40 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by DeWeille et al. (US 6,287,859).

DeWeille et al. disclose the proton gated cation channel from sensory neurons (SEQ ID NO: 14) which has 99.4% amino acid sequence identity with SEQ ID NO: 2. The channels of DeWeille et al. inherently have the P2X2 ATP channel activity as well as the functional activity including amelioride inhibition. The channels of DeWeille et al. inherently belong to the degenerin family.

Applicants argue that presently claimed subject matter has priority date earlier than the earliest priority date of February 11, 1998 of DeWeille et al. However, the priority has been denied as discussed above.

8. Claims 38, 40 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Renard et al. (US 2002/0173000).

Renard et al. disclose the proton gated cation channel from sensory neurons (SEQ ID NO: 6) which has 94.9% amino acid sequence identity with SEQ ID NO: 2.

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The channels of Renard et al. inherently have the P2X2 ATP channel activity as well as the functional activity including amelioride inhibition. The channels of Renard et al. inherently belong to the degenerin family.

Applicants argue that presently claimed subject matter has priority date earlier than the earliest priority date of May 15, 1998 of Renard et al. However, the priority has been denied as discussed above.

9. Claims 16-21 and 41 are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879.

The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Michael Pak
Primary Examiner
Art Unit 1646
August 22, 2005